Paper No. 38

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte MARK L. TYKOCINSKI
and JOSEPH ILAN

_____

Appeal No. 1999-0326
Application No. 07/997,715[1]

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HEARD: October 11, 2001

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Before SCHEINER, MILLS and GRIMES, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 28 through 31, all of the claims remaining in the application.

[1] Application for patent filed December 31, 1992. According to appellants, this application is a continuation-in-part of application serial no. 07/872,712, filed April 20, 1992, now abandoned.

Claim 28 is representative of the subject matter on appeal and reads as follows:

28. A method for inducing an anti-tumor immune response against a tumor cell in a patient comprising:

administering to said patient having said tumor cell a heterologous tumor cell of the same tumor type wherein one said heterologous tumor cell has a reduced intracellular level of IGF-I relative to the level of IGF-I normally expressed in said heterologous tumor cell, and

wherein said reduction in the intracellular level of IGF-I results in said heterologous tumor cell inducing an anti-tumor immune response when administered to said patient.

The Rejection

Claims 28 through 31 stand rejected under 35 U.S.C. § 112, first paragraph as based on a non-enabling disclosure. In support of the rejection, the examiner relies on Uhlmann and Peyman, "Antisense Oligonucleotides: A New Therapeutic Principle," Chemical Reviews, Vol. 90, No. 4, pp. 544-579 (June 1990). See the Second Supplemental Examiner's Answer (paper no. 28).

Deliberations

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification; appellants' Brief on Appeal (paper no. 20); the Examiner's Answer (paper no. 21); appellants' Reply Brief (paper no. 23); the amendment entitled "Second Supplemental Amendment," filed August 14, 1996 (paper no. 25); the Supplemental Examiner's Answer (paper no. 26); appellants' Reply to Supplemental Examiner's Answer (paper no. 27); the Second Supplemental Examiner's Answer (paper

no. 28); and the above-cited reference. We note that claims 28 through 31, the only claims under appeal, were newly presented in the Second Supplemental Amendment.

On consideration of the record, including the materials listed above, we reverse the examiner's rejection under the first paragraph of 35 U.S.C. § 112.

Discussion

According to the examiner, "[t]he sole remaining issue of non-patentability . . . is the scope of enablement," inasmuch as "the only means of inhibiting expression of IGF-I . . . taught in the specification is . . . a single gene construct," i.e., the anti-sense nucleic acid construct pANTI-IGF-I, and it would have required undue experimentation to inhibit IGF-I expression by any other means. Second Supplemental Examiner's Answer, pages 1 and 2.

"When rejecting a claim under the enablement requirement of section 112, the PTO bears the burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification . . . ; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement." In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

The examiner offers two reasons in support of his conclusion that the specification is not broadly enabling for inhibiting IGF-I expression, neither of which is consistent with the evidence of record.

First, the examiner argues "[a]s noted in the Examiner's Answer mailed 1 March 1996," that "the design and utilization of anti-sense nucleic acids was a highly unpredictable art . . . requir[ing] extensive experimentation in the elaboration of appropriate nucleic acid constructs that when introduced into a host cell would effect an inhibition of expression of any particular gene or gene product." Second Supplemental Examiner's Answer, page 2. Turning to the Examiner's Answer, we note that page 576 of Uhlmann is relied on as evidence of unpredictability. Uhlmann describes a number of variables affecting "[t]he efficiency with which the function of a target sequence can be inhibited," but at the same time, describes several routine approaches to selecting effective target sequences.

As explained in PPG Indus. Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996) (quoting Ex parte Jackson, 217 USPQ 804, 807 (Bd. App. 1982)), "[t]he fact that some experimentation is necessary does not preclude enablement . . . [t]he test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine . . . " See also In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) ("That some experimentation may be required is not fatal; the issue is whether the amount of experimentation required is 'undue.'" (emphasis in original). While identifying inhibitory nucleic acid constructs other than pANTI-IGF-I might involve a considerable amount of trial and error, in our view, the empirical experimentation described by Uhlmann is fairly described as routine.

Second, in the statement of the rejection, the examiner argues that the specification provides "[n]o other guidance . . . as to how any other means of inhibiting IGF-I expression would have been accomplished." Second Supplemental Examiner's Answer, page 2. While it is true that the specification indicates that "a preferred method of reducing [IGF-I] expression is by antisense technology," it also indicates that "[o]ther methods . . . can be used, including use of specific antibodies." Specification, page 8. The examiner, in responding to appellants' arguments, acknowledges that the specification suggests several additional methods of inhibiting IGF-I expression, but merely dismisses them as "entirely prophetic in nature" and "necessitat[ing] that the artisan exercise undue experimentation." As stated in In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 369-70 (CCPA 1971) (citations omitted):

> [I]t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.

In our view, the examiner has failed to explain why those of ordinary skill in the art would have been unable to reduce IGF-I expression using specific antibodies, as described in the specification. In addition, we note that several of the reasons given by the examiner in support of his conclusion are not relevant to the claimed method, which merely

requires ex vivo inhibition of IGF-I expression[2] (e.g., "[I]f the inhibitor were administered in vivo how would one have targeted it's [sic] effect to the cell of interest?" Second Supplemental Examiner's Answer, page 4). Under these circumstances, it is not reasonable to shift the burden to appellant to substantiate the truth of statements in the specification.

Having considered the record as a whole, we conclude that the examiner's position is not supported by the evidence. Accordingly, the rejection of claims 28 through 31 for lack of enablement is reversed.

REVERSED

Toni R. Scheiner	)
Administrative Patent Judge	)
	)
	) BOARD OF PATENT
Demetra J. Mills	)
Administrative Patent Judge	) APPEALS AND
	)
	) INTERFERENCES
Eric Grimes	)
Administrative Patent Judge	)

[2] Claims 28 through 31 require administration of a tumor cell having a reduced intracellular level of IGF-I relative to the level of IGF-I normally expressed in the tumor cell. Thus, the tumor cell is administered after "expression of the factor [is] inhibited . . . in vitro." Specification, page 12.

Richard J. Warburg
Foley & Lardner
P.O. Box 80278
San Diego, CA 92138